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Billing Code 6355-01P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Metal-Cored Candlewicks Containing Lead and Candles With Such Wicks; Final Rules

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rules.

SUMMARY: The Commission is today declaring that metal-cored candlewicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks are hazardous substances and is banning such wicks and candles with such wicks.¹ The Commission is issuing these final rules under authority of the Federal Hazardous Substances Act (FHSA).

DATES: These final rules becomes effective on [insert date 180 days after publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Kristina Hatlelid, Ph.D., M.P.H., Project Manager, Directorate for Health Sciences, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504-7254.

SUPPLEMENTARY INFORMATION:

¹The Commissioners voted [insert results of Commission vote] to issue these final rules.

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A. Background

On February 24, 2000, the U.S. Consumer Product Safety Commission (CPSC or Commission) received a request from Public Citizen that the Commission ban candles with lead-containing wicks and wicks sold for candle-making that contain lead. On February 29, 2000, CPSC received a similar request from the National Apartment Association and the National Multi Housing Council. These requests were docketed collectively under the FHSA (Petition No. HP 00-3) on March 17, 2000.

After analysis of the available data on lead-cored candlewicks and the information provided by the petitioners, the CPSC staff transmitted a briefing package to the Commission recommending that it proceed with a rulemaking that could result in a ban of lead-cored candlewicks and candles with such wicks. The staff recommended that a lead-cored wick be defined as a wick containing a metal core with greater than 0.06 percent lead by weight in the metal, since laboratory test data indicate that burning candles with metal-cored wicks with lead concentrations of 0.06 percent or less by weight does not result in detectable emissions of lead into the air. In February 2001, the Commission voted

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to grant the petition and commence rulemaking by issuing an advance notice of proposed rulemaking (ANPR) incorporating this criterion. 66 FR 10863. The ANPR was followed in April of 2002 by a notice of proposed rulemaking (NPR) that included requirements for certification, record-keeping, labeling, and tracking of metal-cored candlewicks and candles that comply with the ban. 67 FR 20062.

B. The Product²

Lead-cored wicks are candlewicks with a metal wire in the center made of lead or lead alloy. The metal core is used to provide structural rigidity to the wick, i.e., to keep the wick straight during candle production, and to provide an upright wick during burning.

C. The Market

1. Trade Associations

The major trade association that represents candle and wick manufacturers and suppliers is the National Candle Association (NCA). NCA members include about 74 candle

² Information presented in this preamble is derived from briefing memoranda to the Commission from Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences, to the Commission, "Petition HP 00-3 to Ban Lead-cored Candlewicks," December 12, 2000; "Proposal to Ban Lead-Cored Candlewicks," March 18, 2002; and "Briefing Package for Ban of Candles with Lead-containing Wicks and Wicks for Candle-making that Contain Lead -- Final Rule," [insert date of final rule briefing package], 2003. These and other materials for this rulemaking are available on the CPSC world wide web site at www.cpsc.gov and from the CPSC Office of the Secretary, Room 502, 4330 East West Highway, Bethesda, Maryland, 20814, (301) 504-7923.

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manufacturers, ten of which are foreign. The NCA states that its members produce about 90 percent of the candles made in the U.S. Another U.S. based organization, comprised of craftspersons, is the International Guild of Candle Artisans, with 800 members from around the world.

2. *Candle Information*

Of 483 firms identified by CPSC staff as U.S. candle manufacturers, all but three firms had fewer than 500 employees and 293 (or 60 percent) had fewer than five employees.

In 2000, the latest year for which factory shipment data are available, U.S. domestic candle shipments totaled approximately \$1.5 billion. Imports amounted to \$504 million in 2000 with candles from the Far East accounting for almost half of the imports. U.S. exports of candles amounted to about \$60.5 million in 2001. The apparent U.S. consumption of candles in 2000 (domestic shipments plus imports, minus exports) was about \$2.0 billion.

Retail prices of candles range from about 10 cents for a small tealight candle up to \$75.00 for large columnar candles.

There are limited data available concerning use of

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candles in homes. According to the NCA, candles are used in 70 percent of U.S. households. They are burned one to three times a week by the majority of candle consumers. Half of the consumers burn one or two candles at a time.

3. *Candlewick Information*

There are three general types of candlewicks. Flat braided wicks, used in taper candles, make up about 50 percent of U.S. wick production. Square wicks, representing less than 10 percent of U.S. production, are used in production of beeswax candles and candles that develop small wax pools when burning. Cored wicks, which account for about 40 percent of wicks used in candles, are rigid and have a central core made of cotton, paper, hemp, metal, or polypropylene, surrounded by wicking material made of paper or fiber. The cores provide rigidity to wicks in candles that produce deep pools of molten wax, and are frequently used in votives, pillars, tealights, and other container candles.

CPSC staff identified three domestic producers of candlewicks. The leading producer accounts for the majority of wicks used by the U.S. candle industry. In addition, there may be several small specialty producers of wicks.

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Candlewick manufacturers sell their wicks to wholesalers (candle material suppliers) or large candle manufacturers. Some wholesale wick suppliers repackage wicks supplied by large producers. The CPSC staff has identified 55 wholesale suppliers of candle making materials. Small candle producers usually purchase wick material from wholesale firms.

Small quantities of candlewicks may be purchased by consumers at craft stores. They may be purchased in large quantities from wholesale firms or direct from manufacturers. Wicks are available on reels or precut to desired lengths. Prices vary depending upon how the wick is supplied and the quantities ordered. For example, based on one manufacturer's list prices, pre-waxed wicks on reels were 12 cents per yard and pre-waxed, pre-cut, two-inch wicks were 37 cents per yard. For this manufacturer, price did not depend on wick type.

No specific information is available for domestic shipments or sales of candlewicks. However, based on information provided by the leading domestic candlewick manufacturer in its comments on the NPR, the CPSC staff estimates that total domestic sales of candlewicks could be

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about four to five million dollars annually. Data on international trade in wicks do not distinguish candlewicks from other types of wicks (e.g., wicks for stoves, lighters, and lamps). Still, imports of all types of wicks, including candlewicks, were about \$4.1 million in 2001.

Prior to the granting of the petition, candlewicks with some levels of detectable lead were found in the marketplace. In a non-statistical survey of candles for sale in the Washington, D.C. area in 1999, the petitioners found that about 30 percent of candles for sale had metal-cored wicks, and about 10 percent of these (or three percent of all candles sampled) had detectable levels (i.e., at least trace levels) of lead in the wick.

According to the NCA, use of lead cored wicks among U.S. manufacturers is negligible. Practically all metal-cored wicks currently produced in the U.S. are made of zinc. According to the NCA, zinc-cored wicks account for about 15 to 20 percent of U.S. production. Zinc-cored wicks have trace amounts of lead, about 0.01 percent, substantially less than the lead limit in the standard finalized today.

D. The Risk of Illness

As a lead-cored wick candle burns, some of the lead may

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vaporize and be released into the air. This airborne lead may be inhaled. Some of this lead may deposit onto floors, furniture, and other surfaces in the room where children may be exposed to it. One cannot tell by looking at the wick core if it is made of lead, and there is no simple way for a consumer to determine its lead content. The presence of lead in a wick can be determined only by laboratory analysis.

Similarly, one cannot tell if lead is being released from a burning candle by observing smoke or soot; nor can one tell that lead is not being released by the lack of visible emissions. Determination of lead in room air or on surfaces must be done by professionals.

The toxic effects of lead and the risk to consumers, especially children, from exposure to lead emitted from lead-cored wick candles, including neurological damage, delayed mental and physical development, attention and learning deficiencies, and hearing problems, were detailed in the CPSC staff briefing packages on Petition No. HP 00-3. CPSC staff concluded that, under reasonable assumptions, exposure of children to indoor air lead levels from candles emitting 430 micrograms of lead per hour or more could

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result in elevated blood levels (greater than 10 micrograms of lead per deciliter of blood). Laboratory investigations by CPSC staff and others indicate that lead-cored wick candles can emit more than 3,000 µg of lead per hour during candle burning. Thus, the Commission finds that, under certain expected use conditions, the lead emitted from burning candles with lead-cored wicks presents a risk to consumers of substantial illness from exposure through inhalation of airborne lead. Children may also be exposed to lead that deposits onto surfaces in the room.

E. International Activities

Several countries have acted on this issue. Officials in Canada issued an advisory in January, 2001, warning consumers that some candles sold in Canada contained lead-cored wicks, and offering advice on making informed purchasing decisions.³ Officials in Australia and New Zealand instituted provisional bans on candles with wicks containing any amount of lead as early as 1999.⁴ Australia recently announced a permanent ban on sales of candles with

³ Health Canada Advisory 2001-02, January 2001.

⁴ Commonwealth of Australia Consumer Protection Notice No. 11 of 1999 under the Trade Practices Act of 1974, September 1999; New Zealand Ministry of Consumer Affairs Unsafe Goods Notice under the Fair Trading Act 1986, June 2000.

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wicks containing more than 0.06 percent lead.⁵

Denmark issued a comprehensive order in December 2000 banning a number of products containing lead.⁶ Chafing dish candles and other candles are specifically included in the ban. The order defines a lead-containing product as one in which lead represents more than 100 mg/kg (0.01 percent) of the homogeneous components.

F. Statutory Requirements

This proceeding is conducted under provisions of the FHSA. 15 U.S.C. 1261-1278. It involves two actions. First, pursuant to section 3(a) of the FHSA, the Commission is declaring that metal-cored candlewicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks are hazardous substances. 16 CFR 1500.12(a)(2). Second, pursuant to section 2(q)(1)(B) of the FHSA, the Commission is banning such wicks and candles with such wicks. 16 CFR 1500.17(a)(13).

A proceeding to declare a substance to be a "hazardous substance" under section 3(a) of the FHSA is governed by,

⁵ Press Release No. 057, Senator Ian Campbell, Parliamentary Secretary to the Treasury, Commonwealth of Australia, November 1, 2002.

⁶ Statutory Order No. 1012 of November 13, 2000, on Prohibition of Import and Marketing of Products Containing Lead, Ministry of Environment and Energy, Danish Environmental Protection Agency.

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inter alia, sections 701(e), (f), and (g) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 371(e)-(g). See 15 U.S.C. 1262(a)(2).

The Commission is declaring that metal-cored candlewicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks are "hazardous substances" within the meaning of section 2(f)(1)(A) of the FHSA because they are toxic, and "may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use...." 15 U.S.C. 1261(f)(1)(A). The basis for this declaration is stated in Section D. of this preamble, *The Risk of Illness*.

Under section 2(q)(1)(B) of the FHSA, the Commission may classify as a "banned hazardous substance" any hazardous substance intended for household use which, notwithstanding the precautionary labeling required by the FHSA, presents such a hazard that keeping the substance out of interstate commerce is the only adequate means to protect the public health and safety. 15 U.S.C. 1261(q)(1)(B). A proceeding to classify a substance as a banned hazardous substance under section 2(q)(1)(B) of the FHSA is governed by the

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requirements set forth in section 3(f) of the FHSA, and also by sections 701(e), (f), and (g) of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 371(e)). See 15 U.S.C. 1261(q) (2) and 1262(f).

The CPSC Human Factors staff analysis on the issue of precautionary labeling of individual candles concludes that labeling is not an acceptable strategy for protecting vulnerable populations from lead poisoning that may be caused by burning candles with lead-cored wicks.⁷

That analysis shows that since lead is emitted in unpredictable amounts from a candle with a metal-cored wick containing more than 0.06 percent lead in the metal when the candle is used as intended, the only preventative measures consumers could take to protect themselves against the hazard would be to not burn candles with such wicks. No label or subsequent action by the consumer would prevent the release of lead into the air if the candle were used as intended. The Commission therefore finds that, notwithstanding the precautionary labeling required by the FHSA, metal-cored candlewicks containing more than 0.06

⁷ See fn. 2 for sources for the CPSC staff analyses related to this rulemaking.

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percent lead in the metal and candles with such wicks present a hazard such that keeping them out of interstate commerce is the only adequate means to protect the public health and safety.

In addition to today's final rule banning these wicks and candles, the FHSA requires that the Commission publish a final regulatory analysis that includes: (1) a description of the potential costs and benefits of the rule; (2) a description of alternatives considered by the Commission (including a description of their potential costs and benefits and an explanation of why they were not chosen); and (3) a summary of significant issues raised by comments on the preliminary regulatory analysis published with these proposed rules. 15 U.S.C. 1262(i)(1). The Commission must also find that: (1) any relevant voluntary standard is unlikely to adequately reduce the risk of injury or substantial compliance with the voluntary standard is unlikely; (2) the expected benefits of the regulation bear a reasonable relationship to expected costs; and (3) the regulation imposes the least burdensome requirement that would adequately reduce the risk of injury. 15 U.S.C. 1262(i)(2).

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Procedures established by section 701(e) of the FDCA govern this Commission action to finalize the hazardous substance declaration and the banning rule. 15 U.S.C. 1262(a)(2) and 1261(q)(2). These procedures provide that once the Commission issues a final rule, persons who would be adversely affected by the rule have a period of thirty (30) days in which to file objections stating reasonable grounds therefor, and to request a public hearing on those objections. 21 U.S.C. 371(e). Should valid objections be filed, a hearing to receive evidence concerning the objections would be held and the presiding officer would issue an order after the hearing, based upon substantial evidence. 21 U.S.C. 371(e); 16 CFR Part 1502.

G. Response to Comments on the NPR

Six comments were received in response to the NPR. All six comments were in favor of a ban on lead-cored wicks. One commenter expressed interest in allowing the use of lead-cored candlewicks in certain circumstances.

One wick manufacturer (Atkins and Pearce) and two industry groups (Consumer Specialty Products Association, National Candle Association) provided comments. One commenter represented a non-profit information and advocacy

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group in Australia (Global Lead Advice and Support Service). Two commenters were individual consumers or interested parties.

1. *Federal Regulation*

Comments: All six commenters support the concept of regulating the use of lead in metal-cored candlewicks, although there was disagreement about the scope of the proposed regulation, and the proposed requirements for testing, certifying, and tracking metal-cored wicks.

Response: The Commission acknowledges the interest among consumers, industry, and advocacy groups in the elimination of candlewicks as a source of lead exposure. Responses to specific questions and comments about the proposed rule are set forth below.

2. *Proposed Record-Keeping Requirements*

Comments: The rule as proposed included requirements that shipping cartons of metal-cored candlewicks and shipping cartons of candles with such wicks be labeled as complying with the ban and with a lot number or other designation, and that wick and candle manufacturers, importers, and distributors maintain records documenting compliance with the ban for each lot. Representatives from industry

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expressed concern about the costs and labor that would be involved in the tracking of metal-cored wicks used in specific candles, and the maintenance of records.

These commenters provided some information about the candle-making process to illustrate potential difficulties with the proposed requirements. For example, the commenters described machines that rapidly produce many candles at once, simultaneously drawing candlewick from several different spools. Consequently, a batch of finished candles could contain wicks from different lots or sources. Further, these candles with different wicks would be indistinguishable and would be packaged together at the end of production. Thus, a single shipping carton could contain identical candles with different lots of metal-cored candlewicks. The commenters believe it would be labor intensive and costly to change the current method of production so that individual lots of wicks could be separated and tracked. While not providing alternative estimates of costs, the commenters indicated that the staff may have underestimated the costs of the labeling and record-keeping requirements.

Response: On the basis of comments received and the CPSC

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staff's further analysis of the complex manufacturing processes described by the commenters and the limited benefits expected, the final rule issued today does not require record-keeping and tracking.

Comment: One commenter, a US wick manufacturer, suggested that tracking could be done in ways other than labeling shipping cartons with a lot number or other identifier. For example, if the wicks in specific lots, made with specific lots of metal-core material (e.g., zinc wire), could be visually distinguished from each other, manufacturers could track candlewick lots without changing current manufacturing processes. One way to distinguish wick lots would be to incorporate unique colors and patterns into the wick braid. Thus, inspecting the wicks in candles from a specified manufacturer would provide visual information about the wick lot. Multiple wick lots could be used at the same time in candle production, and multiple wick lots could end up in the same shipping carton, without losing the ability to obtain records for specific candles or track specific lots of metal-cored wicks. However, additional information provided by this commenter indicated that the use of color-coded tracer threads in the candlewick could result in

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increased costs associated with testing the performance of the new candlewicks before they could be used in candle production.

Response: The final rule issued today does not require the record-keeping and tracking proposed in the NPR.

3. *Effective Date*

Comment: One commenter stated that non-complying products should not benefit from an extended sell-through period.

Response: The Commission has no reason to believe that manufacturers, importers, or retailers have, or will, warehouse or stockpile candles made prior to the effective date that would not conform to the rule. Similarly, the Commission has no information that suggests that manufacturers, importers, or retailers will stockpile non-complying candlewicks for the purposes of producing candles between issuance of the final rule and the effective date. Moreover, non-complying candlewick inventory would not be usable after the effective date. The 180-day effective date provides time for manufacturers, distributors, and importers to make any necessary changes to bring their products and shipping containers into compliance with the regulation.

4. *Lead-Cored Candlewicks are Superior for Some Uses*

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Comment: A commenter stated that candles with lead-cored wicks performed better than candles with other kinds of wicks in a specific application (camping lanterns), and suggested that an exemption be made to allow specific uses of lead-cored candlewicks in candles.

Response: Additional information provided by this commenter indicates that the candles in question do not actually contain lead-cored wicks.

5. *All Metals Should be Banned for Use in Candlewicks*

Comment: One commenter, representing an information and advocacy group in Australia, suggested that all metal-cored wicks should be banned for use in candles to avoid any confusion about whether the metal contains unacceptable levels of lead.

Response: As discussed in the CPSC staff briefing memoranda, laboratory test data show that burning candles with metal-cored wicks with lead concentrations of 0.06 percent or less by weight does not result in detectable emissions of lead into the air. Therefore, there is no basis for declaring all metal-cored candlewicks and candles with such wicks to be hazardous substances.

H. *Alternatives to the Ban*

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1. No Action

If the Commission took no action, lead-cored candlewicks could continue to be sold in the U.S. In the mid-1970's the domestic candle industry stopped using lead in wicks, but lead-cored wicks reappeared on the domestic market some time thereafter. While the domestic industry states that it has now voluntarily eliminated lead in wicks, imports may continue to be a source of lead in the absence of a mandatory standard. Under a no action scenario, CPSC enforcement staff would be limited to taking action against lead-containing wicks under the FHSA on a case-by-case basis.

2. Voluntary Standards

In 1974, the Candle Manufacturers Association industry group submitted a statement informing the Commission of an agreement among candle manufacturers to convert to substitutes for lead-cored wicks in candles by the end of the third quarter 1974. They also agreed not to import candles with lead-cored wicks. Further, the major domestic wick manufacturer at that time agreed to discontinue the production of lead-cored wicks.

Despite this agreement, some wick manufacturers resumed

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producing lead-cored wicks and some candle manufacturers resumed producing and importing candles with lead-cored wicks after 1974.

In May 2000, a task group for candlewicks was formed under the ASTM F15.45 Candle Products Subcommittee to develop a consensus standard to address the lead content of candlewicks. The task group stopped their standards development process in February 2001 in favor of supporting the CPSC mandatory rulemaking process.

During the public comment period on the ANPR, Voices of Safety International (VOSI) proffered a voluntary standard for lead in candlewicks. CPSC technical staff reviewed the standard and noted a number of difficulties. Although the standard stated that a maximum of 0.01 percent lead is required to protect consumer health, no technical or health basis for this level was provided. The CPSC staff maintains that the limit of 0.06 percent lead by weight in the metal is appropriate and supported by the laboratory analyses performed by CPSC staff and others.

The CPSC staff further states that the analytical methodology in the submitted standard is not capable of reliably determining either the presence or concentration of

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lead in metal-cored candlewicks. The CPSC staff concludes that the tensile strength of a metal alloy would not definitively identify zinc cored wicks with less than the maximum allowable lead content in the metal, but could falsely detect alloys not containing lead, causing them to fail the test and be needlessly prohibited from wick use. The staff states that the metal's lead content, not its physical attributes, is the important characteristic in protecting consumers' health.

The VOSI standard specifies different standards for domestic and imported products. A discriminatory approach to imports with no basis in fact would in all likelihood be a violation of the North American Free Trade Agreement (NAFTA), if not other U.S. treaty obligations.

The Commission believes that membership in standards organizations, such as ASTM, serves, in part, to transmit applicable standards to member firms. VOSI offered no information that its members include candle or wick manufacturers. Nor has it provided any evidence that there would be substantial compliance with the voluntary standard.

Based on the foregoing analysis, the Commission finds that the VOSI standard is technically unsound, and thus

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would not result in the elimination or adequate reduction of the risk, and that substantial compliance with it is unlikely.

3. *Precautionary Labeling*

AS discussed above in Section F. of this preamble, *Statutory Requirements*, the CPSC Human Factors staff analysis on this issue demonstrates that precautionary labeling of individual candles is not an acceptable strategy for protecting vulnerable populations from lead poisoning that may be caused by burning candles with lead-cored wicks.

I. **Regulatory Analysis**

1. *FHSA Requirement*

The Commission is issuing a rule declaring a ban on metal-cored wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks. Section 3(i) of the FHSA requires that the Commission prepare a final regulatory analysis for this action. 15 U.S.C. 1262(i). The following discussion addresses this requirement.

2. *Introduction*

The Commission is amending the FHSA regulations to declare that metal-cored wicks containing more than 0.06

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percent lead by weight in the metal and candles with such wicks are hazardous substances and to ban such wicks and candles. In February 2001, the Commission voted to issue an ANPR that could lead to such a declaration and ban. 66 FR 10863. In April 2002, the Commission issued proposed rules that would declare such wicks and candles with such wicks to be hazardous substances and would ban them. 67 FR 20062.

3. Required Content of the Regulatory Analysis

To issue the ban rule under the FHSA, the Commission must also publish a final regulatory analysis containing a discussion of various factors. These factors include a description of the potential benefits and potential costs of the rule, including any benefits and costs that cannot be quantified in monetary terms, and an identification of those most likely to receive the benefits and bear the costs. The FHSA also requires a description of any reasonable alternatives to the rule, together with a summary description of their costs and benefits, and a brief explanation of why such alternatives were not chosen. 15 U.S.C. 1262(i). In addition, the Commission must address the requirements of the Regulatory Flexibility Act, which considers effects on small firms, and the requirement for

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review pursuant to the National Environmental Policy Act.

4. *Analysis of Hazardous Substance Ban*⁸

(a) *Benefits.*

While the benefits to consumers of eliminating lead-cored candlewicks as a source of lead exposure are not quantifiable, they are likely to be small since few lead-cored candlewicks are now produced and/or sold in the U.S. The likely benefits are dependent on individual circumstances of candle use. Laboratory studies indicate that under certain conditions of use exposure to airborne lead from burning candles with lead-cored wicks presents a risk of lead poisoning. Therefore, a ban may result in positive health benefits in individual cases.

In the mid-1970s, the Commission chose to defer to the industry's voluntary agreement to eliminate lead from candlewicks. Since this agreement did not prevent companies from returning to the use of lead-cored wicks in the 1980s and 1990s, a ban on the use of lead in candlewicks will help ensure that lead will not be used in candlewicks in the

⁸ The following discussion of costs and benefits is extracted from Memorandum from Mary F. Donaldson, CPSC Directorate for Economic Analysis to Kristina Hatlelid, CPSC Directorate for Health Sciences, "Final Regulatory Analysis of a Proposed Ban of Lead in Candlewicks," March 10, 2003. See fn. 2 for information on the availability of this and other related documents for this rulemaking.

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future.

(b) Costs.

The costs of replacing lead-cored candlewicks with non-leaded wicks are expected to be small. The current use of lead in wicks is already small, since none of the NCA members use lead in their wicks beyond the acceptable trace levels found in zinc cores, and information obtained from an industry source indicates that the costs of substitutes for lead-cored wicks are not higher than costs of wicks made with lead.

There may be costs associated with labeling and ensuring conformance. Shipping carton labeling may be done by direct printing onto the carton or by affixing a pre-printed label, such as a sticker. On a per carton basis, direct printing is expected to be less costly than the use of a sticker. Labeling machines may cost as much as \$15,000 and individual labels may cost five to ten cents each. Assuming that 15-20 percent of all candles produced would be affected, and that each shipping carton holds 144 candles, valued at one dollar each, perhaps two to three million shipping cartons would require labeling annually. If labels cost five to ten cents each, then annual costs would be

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about \$100,000 to \$300,000. The costs to candlewick manufacturers to label shipments of metal-cored candlewicks, expected to be substantially less than that of candles, are estimated to be about \$80 to \$320 per year.

Consistent with the Commission's lead in consumer products guidance policy at 16 CFR 1500.230, domestic producers, distributors, private labelers, importers, and retailers of metal-cored candlewicks and candles with such wicks may wish to test products to ensure compliance with the regulation. Alternatively, firms may wish to obtain assurances from suppliers that the lead content of the metal does not exceed 0.06 percent by weight. This should be relatively straightforward because candlewick manufacturers generally receive chemical analyses from the suppliers of the metal used in their candlewick production.

Finally, there may be costs associated with inventories of non-complying candlewicks held by manufacturers. The rule would apply to candlewicks or candles manufactured on and after the rule's effective date. Therefore, non-complying candlewicks would have to be scrapped under the regulation since they would no longer be usable in candle manufacturing on and after the effective date. It is not anticipated,

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however, that a large amount of candlewick inventory would be affected.

In summary, while the benefits of a ban of lead in candlewicks are likely to be small, the costs of the ban to the industry are small, and thus bear a reasonable relationship to the benefits. The action will contribute to the gradual reduction in lead exposure in the U.S. population.

5. Alternatives to the Rule

The Commission has considered several other alternatives, including: no action, product labeling, recordkeeping for wick/candle shipments and deferral to a voluntary standard. See discussions above at Section G., *Response to Comments on the NPR*, and Section H., *Alternatives to Proposed Ban*.

J. Paperwork Reduction Act

The ban regulation as proposed would have required manufacturers and importers of metal-cored candlewicks and candles with such wicks to perform testing or obtain records of testing, maintain records, and label shipping containers for metal-cored candlewicks and candles with such wicks that they produce or import. For this reason, the proposed rule

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contained "collection of information requirements," and would have been subject to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501-3520.

As noted above in Section G., *Response to Comments*, the Commission has elected to delete these recordkeeping requirements from the final rule issued today. Accordingly, the rule as finalized is not subject to the PRA.

K. Regulatory Flexibility Act Certification

When an agency issues a final rule such as the ban on lead-cored candlewicks and candles with such wicks, the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 et seq., generally requires the agency to prepare a final regulatory flexibility analysis describing the impact of the rule on small businesses and other small entities. Section 605 of the RFA provides that an agency is not required to prepare a regulatory flexibility analysis if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of a rule to

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declare that metal-cored wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks are hazardous substances and to ban such wicks and candles. A copy of the preliminary analysis is available for inspection in the docket for this rulemaking. That assessment reported that the costs to consumers and candlewick and candle manufacturers were likely to be small.

After analyzing the comments received in response to the NPR, the CPSC staff has concluded that the incremental cost of the rules issued today is likely to be small. Accordingly, it is unlikely that the rules will have a substantial effect on a significant number of small businesses.

Based on the foregoing assessment, the Commission certifies that the rules issued today to declare that metal-cored wicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks are hazardous substances and to ban such wicks and candles will not have a significant adverse impact on a substantial number of small businesses or other small entities.

L. Environmental Considerations

Pursuant to the National Environmental Policy Act, and

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in accordance with Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission has assessed the possible environmental effects associated with the hazardous substance declaration and ban for metal-cored candlewicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks.

The Commission's regulations at 16 CFR 1021.5(c)(1) state that rules or safety standards to provide design or performance requirements for products normally have little or no potential for affecting the human environment. Assessment of the impact of the rules issued today indicates that they will have no significant effects on the environment. Thus, the Commission concludes that no environmental assessment or environmental impact statement is required in this proceeding.

M. Effective Date

The rule issued today provides an effective date 180 days after publication in the *Federal Register*. The time before that date may be used for depletion of any existing stocks of candlewick material and candles subject to the ban. The ban then applies to any metal-cored candlewick

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containing more than 0.06 percent lead by weight in the metal, and any candle with such a wick, that is manufactured or imported on or after that date.

N. Executive Order 12988

As provided for in Executive Order 12988 (February 5, 1996), the CPSC states the preemptive effect of these regulations as follows.

The FHSA provides that, generally, if the Commission issues a banning rule under section 2(q) of the FHSA to protect against a risk of illness or injury associated with a hazardous substance, "no State or political subdivision of a State may establish or continue in effect a requirement applicable to such substance and designed to protect against the same risk of illness or injury unless such requirement is identical to the requirement established under such regulations." 15 U.S.C. 1261n(b)(1)(B). Upon application to the Commission, a State or local standard may be excepted from this preemptive effect if the State or local standard (1) provides a higher degree of protection from the risk of injury or illness than the FHSA standard and (2) does not unduly burden interstate commerce. In addition, the Federal government, or a State or local government, may establish

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and continue in effect a non-identical requirement that provides a higher degree of protection than the FHSA requirement for the hazardous substance for the Federal, State or local government's own use. 15 U.S.C. 1261n(b)(2).

Thus, with the exceptions noted above, the rule banning metal-cored candlewicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks preempts non-identical state or local requirements applicable to such wicks and candles designed to protect against the same risk of injury.

O. Conclusion

For the reasons stated in this preamble, the Commission finds that metal-cored candlewicks containing more than 0.06 percent lead by weight in the metal and candles with such wicks are hazardous substances, that cautionary labeling required by the FHSA is not adequate for such wicks and candles, and that, due to the degree and nature of the hazard presented by these items, in order to protect the public health and safety it is necessary to keep them out of commerce.

List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous materials, Hazardous

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substances, Imports, Infants and children, Labeling, Law enforcement, and Reporting and recordkeeping.

For the reasons stated in the preamble, the Commission amends Title 16 of the Code of Federal Regulation to read as follows:

**PART 1500-HAZARDOUS SUBSTANCES AND ARTICLES;
ADMINISTRATION AND ENFORCEMENT REGULATIONS.**

1. The authority for Part 1500 continues to read as follows:

Authority: 15 U.S.C. 1261-1278.

2. In § 1500.12(a), add a new paragraph (2) to read as follows:

(2) metal-cored candlewicks that have a lead content of more than 0.06 percent of the total weight of the metal core, and candles made with such wicks.

3. In § 1500.17(a), add a new paragraph (13) to read as follows:

(13)(i) *Candles made with metal-cored wicks.* Candles manufactured or imported on or after _____, 2003, [insert date 180 days after promulgation of final rule] made with metal-cored candlewicks, unless:

(A) The metal core of each candlewick has a lead

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content (calculated as the metal) of not more than 0.06 percent of the total weight of the metal core; and

(B) Each outer container or wrapper in which candles subject to subparagraph (i)(A) are shipped, including each outer container or wrapper in which such candles are distributed to a retail outlet, is labeled "Conforms to 16 CFR 1500.17(a)(13)." For purposes of this paragraph (B), the term "outer container or wrapper" does not include the immediate container in which candle(s) is/are intended to be displayed at retail or during use in the home, unless that container or wrapper is also the only container or wrapper in which the candle(s) is/are shipped to a retailer.

(ii) *Metal-cored candlewicks.* Metal-cored candlewicks manufactured or imported on or after _____, 2003, [insert date 180 days after promulgation of final rule] unless:

(A) The metal core of each candlewick has a lead content (calculated as the metal) of not more than 0.06 percent of the total weight of the metal core; and

(B) Each outer container or wrapper in which candlewicks subject to paragraph (ii)(A) above is shipped, including each outer container or wrapper of a shipment distributed to

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a retail outlet, is labeled "Conforms to 16 CFR 1500.17(a)(13)." For purposes of this paragraph (B), the term "outer container or wrapper" does not include the immediate container in which candlewick(s) is/are intended to be displayed or sold at retail, unless that container or wrapper is also the only container or wrapper in which the candlewick(s) is/are shipped to a retailer.

(iii) *Findings* -- (A) *General*. To issue a rule under section 2(q)(1) of the FHSA, 15 U.S.C. 1261(q)(1), classifying a substance or article as a banned hazardous substance, the Commission must make certain findings and include them in the regulation. These findings are discussed in paragraphs (a)(13)(iii)(B) through (D) of this section.

(B) *Voluntary Standard*. (1) One alternative to the ban that the Commission considered is to take no mandatory action, and to depend on a voluntary standard. One organization has a standard for candlewicks intended to address the potential for substantial illness posed by such wicks and candles with such wicks. The Commission has found that the standard is technically unsound and that substantial compliance with it is unlikely. Furthermore,

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there is no evidence that the standard has been adopted and implemented by candlewick or candle manufacturers.

(C) *Relationship of Benefits to Costs.* The Commission estimates that the ban will reduce the potential for exposure to lead and resulting lead poisoning because there is no "safe" level of lead in the blood. The annual cost to the candle/wick industry of the ban is estimated by the Commission to be in the range of \$100,000 to \$300,000. On a percentage basis these costs represent only 0.005 to 0.015 percent of the overall value of candle shipments in 2000, which was approximately \$2 billion. Accordingly, the Commission finds that the benefits from the regulation bear a reasonable relationship to its costs.

(D) *Least burdensome requirement.* The Commission considered the following alternatives: no action; labeling all metal-cored candles with wicks containing more than 0.06 percent lead by weight of the metal; recordkeeping for shipments of wicks containing 0.06 percent or less lead by weight of the metal and of candles with such wicks; and relying on the voluntary standard. Neither no action, nor labeling, nor reliance on the voluntary standard would adequately reduce the risk of illness. Recordkeeping for

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shipments of wicks and of candles was not the least burdensome requirement that would prevent or adequately reduce the risk of illness. Therefore the Commission finds that a ban on candlewicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks is the least burdensome requirement that would prevent or adequately reduce the risk of illness.

Dated: _____

Todd A. Stevenson, Secretary
Consumer Product Safety Commission

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List of Relevant Documents

The following documents contain information relevant to this rulemaking, can be accessed on the world-wide web at www.cpsc.gov, and are available for inspection at the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814:

1. Briefing memorandum from Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences, to the Commission, "Petition HP 00-3 to Ban Lead-cored Candlewicks," December 12, 2000.
2. Memorandum from K.M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences, to Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health Sciences, "Review of Lead Emissions from Candles," November 15, 2000.
3. Memorandum from Carolyn Meiers, Engineering Psychologist, Human Factors, to Kristina Hatlelid, Ph.D., M.P.H., Directorate for Health Sciences, "Labeling of Candles with Lead-cored Wicks (Petition HP 00-3)," October 18, 2000.
4. Briefing memorandum from Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences, to the Commission, "Proposal to Ban Lead-Cored Candlewicks," March 18, 2002.
5. Memorandum from Mary F. Donaldson, CPSC Directorate for Economic Analysis to Kristina Hatlelid, CPSC Directorate for Health Sciences, "Preliminary Regulatory Analysis of a Proposed Ban of Lead in Candlewicks," March 5, 2002..
6. "Briefing Package for Ban of Candles with Lead-containing Wicks and Wicks for Candle-making that Contain Lead -- Final Rule," Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences, [insert date of final rule briefing package] _____, 2003.